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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,802	03/20/2001	Kazuya Kawasaki	JG-TT-5053 / 500568.20026	1201

7590 01/17/2003
Jules E. Goldberg, Esq.
Reed Smith LLP
375 Park Avenue
New York, NY 10152

EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 01/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,802

Applicant(s)

KAWASAKI ET AL.

Examiner

Lyle A Alexander

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 specifies an impermeable support and body frame. The reagent is contained within the impermeable body frame. It is not clear how the sample can contact the reagent in the claimed impermeable structure. Additionally, the claim uses the language "without any spreading layer" which is unclear. Exclusion of additional elements can be accomplished by using the language "consisting essentially of" in the preamble.

Claim 3 does not further limit claim 1 because claim 1 states the reagent is within the frame while claim 3 is directed to the reagent in a hydrophilic layer that is on the support.

Claim 7 is directed to an analytical element but fails to claim any reagent capable of performing analysis.

Claim 10 is vague and indefinite as to what type of material is intended by "punching sheet". For the purposes of examination it will be interpreted as a hydrophilic sheet.

Double Patenting

Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 09/858,392. Although the conflicting claims are not identical, they are

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not patentably distinct from each other because both are directed to a dry analytical element without a spreading layer with the reagents in water impermeable element.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 7-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/978,142. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to an analytical device having an impermeable layer and a permeable layer containing the reagent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,6-10 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 356097872A, Sheehy (USP 5,527,712), Neyer(USP 5,725,774) or Sakamoto et al .

The cited prior art all teach a dry analytical element having an impermeable layer and hydrophilic layer.

Claims 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mori et al.

Mori et al. teach a device having an impervious layer and a hydrophilic layer containing the reagent. Applicant's present claim language does not exclude the presence of additional elements, such as a spreading layer, that is taught by Mori et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-5 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over by JP 356097872A, Sheehy (USP 5,527,712), Neyer(USP 5,725,774), Mori et al.(USP 5,709,837) or Sakamoto et al .

The cited prior art is silent to the use of the claimed tetragon and hexagon compartments.

The court decided In re Dailey (149 USPQ 47) "that the configuration of the container is a mere matter of choice " and will not define over a reference having a different shape.

Multiple sided compartments fit well in the confines of a rectangular device and have the advantage better utilizing the area.

It would have been within the skill of the art to modify by JP 356097872A, Sheehy (USP 5,527,712), Neyer(USP 5,725,774), Mori et al.(USP 5,709,837) or Sakamoto et al : and use a tetragon or hexagon shaped compartments to gain the above advantages as a "mere matter of choice" in view of Dailey above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9319 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander
Primary Examiner
Art Unit 1743

January 13, 2003